TITLE 9. HEALTH SERVICES

CHAPTER 4. DEPARTMENT OF HEALTH SERVICES NONCOMMUNICABLE DISEASES

ARTICLE 1. DEFINITIONS

Section
R9-4-101. Definitions, General
R9-4-102. Repealed
R9-4-103. Repealed
R9-4-104. Definitions, Cancer Registry
R9-4-105. Repealed

ARTICLE 2. PESTICIDE ILLNESS

Section
R9-4-201. Definitions
R9-4-202. Pesticide Illness Reporting Requirements

ARTICLE 3. BLOOD LEAD LEVELS

Section
R9-4-301. Definitions
R9-4-302. Reporting Significant Blood Lead Levels

ARTICLE 4. CANCER REGISTRY

Section
R9-4-401. Case Reporting
R9-4-401.01. Pathology Laboratory Reporting
R9-4-402. Filing Requirements
R9-4-403. Data Quality Assurance
R9-4-404. Repealed

ARTICLE 5. BIRTH DEFECTS MONITORING PROGRAM

Section
R9-4-501. Definitions
R9-4-502. Procedures; Permission to Review Patient Records

ARTICLE 1. DEFINITIONS

R9-4-101. Definitions, General

In this Chapter, unless otherwise specified:

1. "Dentist" means an individual licensed under A.R.S. Title 32, Chapter 11, Article 2.
2. "Department" means the Arizona Department of Health Services.
3. "Diagnosis" means the identification of a disease or injury, by an individual authorized by law to make the identification, that is the cause of an individual's current medical condition.
4. "Hospital" means a health care institution licensed by the Department as a general hospital, a rural general hospital, or a special hospital under 9 A.A.C. 10.
5. "ICD-9-CM" means ICD-9-CM: International Classification of Diseases, 9th Revision, Clinical Modification (5th ed. 2000), incorporated by reference, on file with the Department and the Office of the Secretary of State, and available from Practice Management Information Corporation, 4727 Wilshire Boulevard, Suite 300, Los Angeles, CA 90010 and from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. This incorporation by reference contains no future editions or amendments.
6. "Physician" means an individual licensed as a doctor of allopathic medicine under A.R.S. Title 32, Chapter 13 or as a doctor of osteopathic medicine under A.R.S. Title 32, Chapter 17.

Historical Note
Adopted effective September 25, 1991 (Supp. 91-3). Amended by final rulemaking at 6 A.A.R. 2948, effective July 18, 2000 (Supp. 00-3).

R9-4-102. Repealed

Historical Note
Adopted effective August 15, 1989 (Supp. 89-3). Amended effective April 9, 1993 (Supp. 93-2). Section repealed by final rulemaking at 6 A.A.R. 2948, effective July 18, 2000 (Supp. 00-3).

R9-4-103. Repealed

Historical Note
Adopted effective August 15, 1989 (Supp. 89-3). Amended effective March 4, 1993 (Supp. 93-1). Section repealed by final rulemaking at 7 A.A.R. 55, effective December 12, 2000 (Supp. 00-4).

R9-4-104. Definitions, Cancer Registry

In Article 4, unless the context otherwise requires:

1. "Arizona Cancer Registry" (ACR) means the unit of the Department authorized to conduct cancer surveillance.
2. "Cancer clinic" means every health care institution, whether organized for profit or not, which is not a hospital and which provides outpatient cancer diagnosis and treatment of 100 or more cancer cases per year, including outpatient surgical facilities, staff-based health maintenance organizations, multispecialty clinics, and outpatient radiation therapy facilities.
3. "Cancer registry" means a program authorized to receive, collect and maintain information on persons diagnosed with cancer.
4. "Case" means any person with a cancer, or carcinoma in situ, or benign tumor of the central nervous system. This does not include localized skin cancer of the following types: papillary, squamous cell, basal cell, or carcinoma not otherwise specified.
5. "Date of last contact" means the date the case was last known to be alive.
6. "Doctor" means physician or dentist.
7. "Follow-up report" means a standard ACR-supplied form or a diskette that conveys whether the case is alive or dead, the status of the disease and subsequent treatments received by the case.
8. "Registrar" means a person who has two years of experience working in a cancer registry, or two years of experience in medical record discharge analysis, coding, or abstracting, or who has successfully completed a college-level course in anatomy and physiology, and a course in medical terminology.
9. "Stage" means the categorization of the extent of cancer, using the TNM classification scheme.
10. "TNM" means the Tumor size, lymph Node involvement, and distant Metastases codes and classification scheme promulgated by the American Joint Committee on Cancer, *Manual for Staging of Cancer* (3rd Ed.), J.B. Lippincott Company, East Washington Square, Philadelphia, PA 19105, incorporated herein by reference and on file with the Office of the Secretary of State.
11. "Vital status" means whether the patient is alive or dead.

Historical Note
Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3). "Register" corrected to "Registry" in subsection (1) (Supp. 93-1).

R9-4-105. Repealed

Historical Note
Adopted effective September 25, 1991 (Supp. 91-3). Section repealed by final rulemaking at 7 A.A.R. 712, effective January 17, 2001 (Supp. 01-1).

ARTICLE 2. PESTICIDE ILLNESS

R9-4-201. Definitions

In this Article, unless otherwise specified:

1. "Cluster illness" means sickness in two or more individuals that is caused by or may be related to one pesticide exposure incident, as determined by the history, signs, or symptoms of the sickness; laboratory findings regarding the individuals; the individuals' responses to treatment for the sickness; or the geographic proximity of the individuals.
2. "Documented" means evidenced by written information such as pesticide applicator reports, statements of individuals with pesticide illness, or medical records.
3. "Health care professional" means a physician, a registered nurse practitioner, a physician assistant, or any other individual who is authorized by law to diagnose human illness.
4. "Medical director" means the individual designated by a poison control center as responsible for providing medical direction for the poison control center or for approving and coordinating the activities of the individuals who provide medical direction for the poison control center.
5. "Pest" has the same meaning as in A.R.S. Title 3, Chapter 2, Article 5 or as used in A.R.S. Title 3, Chapter 2, Article 6 and A.R.S. Title 32, Chapter 22.
6. "Pesticide" means any substance or mixture of substances, including inert ingredients, intended for preventing, destroying, repelling, or mitigating any pest or intended for use as a plant regulator, defoliant, or desiccant, but does not include an antimicrobial agent, such as a disinfectant, sanitizer, or deodorizer, used for cleaning.
7. "Pesticide illness" means any sickness reasonably believed by a health care professional or medical director to be caused by or related to documented exposure to any pesticide, based upon professional judgment and:
   a. The history, signs, or symptoms of the sickness;
   b. Laboratory findings regarding the individual; or
   c. The individual's response to treatment for the sickness.
8. "Physician assistant" has the same meaning as in A.R.S. § 32-2501.
9. "Poison control center" means an organization that is a member of and may be certified by the American Association of Poison Control Centers.
10. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.

Historical Note
Adopted effective August 15, 1989 (Supp. 89-3). Amended effective April 9, 1993 (Supp, 93-2). Former Section R9-4-201 renumbered to R9-4-202; new Section R9-4-201 adopted by final rulemaking at 6 A.A.R. 2948, effective July 18, 2000 (Supp. 00-3).

R9-4-202. Pesticide Illness Reporting Requirements

A health care professional or medical director who participates in the diagnosis of or identifies an individual with pesticide illness shall file a report of pesticide illness with the Department as follows:

1. The health care professional or medical director shall report a pesticide illness within five working days from the date of diagnosis or identification, except:
   a. The health care professional or medical director shall report a pesticide illness where the individual with pesticide illness is hospitalized or dies no later than one working day from the time of hospital admission or death; and
   b. The health care professional or medical director shall report cluster illnesses no later than one working day from the time the second individual with pesticide illness is diagnosed or identified.
2. The health care professional or medical director shall submit the report to the Department by telephone; in person; in a writing sent by fax, delivery service, or mail; or by an electronic reporting system if an electronic reporting system is developed by the Department. The report shall contain the following information:
   a. The name, address, and telephone number of the individual with pesticide illness;
   b. The date of birth of the individual with pesticide illness;
   c. The gender of the individual with pesticide illness;
   d. The occupation of the individual with pesticide illness, if the documented pesticide exposure is related to the occupation;
   e. The dates of onset of illness and of diagnosis or identification as pesticide illness;
   f. The name of the pesticide, if known;
   g. The name, business address, and telephone number of the health care professional or medical director making the report;
   h. A statement specifying whether the illness is caused by a documented pesticide exposure or is related to a documented pesticide exposure; and
   i. The health care professional's or medical director's reason for believing that the illness is caused by or related to documented exposure to a pesticide.
3. The health care professional or medical director may designate a representative to make the report to the Department on behalf of the health care professional or medical director.

Historical Note
New Section renumbered from R9-4-201 and amended by final rulemaking at 6 A.A.R. 2948, effective July 18, 2000 (Supp. 00-3).

ARTICLE 3. BLOOD LEAD LEVELS

R9-4-301. Definitions

In this Article, unless otherwise specified:

1. "Adult" means an individual 16 years of age or older.
2. "Child" means an individual younger than 16 years of age.
3. "Clinical laboratory" has the same meaning as in A.R.S. § 36-451.
4. "Patient" means the individual whose blood has been tested for lead content.
5. "Public" means funded by and operated under the direction of the federal or state government or a political subdivision of the state.

6. "Public insurance" means a public program, such as the Arizona Health Care Cost Containment System, KidsCare, Indian Health Services, or TRICARE, that pays for medical services.
7. "Whole blood" means human blood from which plasma, erythrocytes, leukocytes, and thrombocytes have not been separated.

Historical Note
Adopted effective August 15, 1989 (Supp. 89-3). Amended effective March 4, 1993 (Supp. 93-1). Former Section R9-4-301 renumbered to R9-4-302; new Section R9-4-301 adopted by final rulemaking at 7 A.A.R. 55, effective December 12, 2000 (Supp. 00-4).

R9-4-302. Reporting Significant Blood Lead Levels

A. A physician who receives a laboratory result showing a level of lead equal to or greater than 10 micrograms of lead per deciliter of whole blood for a child or 25 micrograms of lead per deciliter of whole blood for an adult shall report the blood lead level to the Department as follows:
1. The physician shall report the blood lead level within five working days from the date of receipt of the laboratory result if the blood lead level is less than 45 micrograms of lead per deciliter of whole blood for a child or less than 60 micrograms of lead per deciliter of whole blood for an adult.
2. The physician shall report the blood lead level within one working day from the date of receipt of the laboratory result if the blood lead level is equal to or greater than 45 micrograms of lead per deciliter of whole blood for a child or equal to or greater than 60 micrograms of lead per deciliter of whole blood for an adult.
3. A physician may designate a representative to make the report to the Department on behalf of the physician.

B. A clinical laboratory director shall report to the Department the results of all tests for lead in whole blood as follows:
1. The clinical laboratory director shall report the blood lead test result within five working days from the date of completing the test if the blood lead level is equal to or greater than 10 but less than 45 micrograms of lead per deciliter of whole blood for a child or equal to or greater than 25 but less than 60 micrograms of lead per deciliter of whole blood for an adult.
2. The clinical laboratory director shall report the blood lead test result within one working day from the date of completing the test if the blood lead level is equal to or greater than 45 micrograms of lead per deciliter of whole blood for a child or equal to or greater than 60 micrograms of lead per deciliter of whole blood for an adult.
3. The clinical laboratory director shall report blood test results that are less than 10 micrograms of lead per deciliter of whole blood for a child or less than 25 micrograms of lead per deciliter of whole blood for an adult at least once each month.
4. A clinical laboratory director may designate a representative to make the report to the Department on behalf of the clinical laboratory director.

C. A physician or clinical laboratory director shall submit each report to the Department by telephone; in a writing sent by fax, delivery service, or mail; or by an electronic reporting system authorized by the Department.

D. A report shall include the following information:
1. The patient's name, address, and telephone number;
2. The patient's date of birth;
3. The patient's gender;
4. If the patient is an adult, the patient's occupation and the name, address, and telephone number of the patient's employer;
5. An indication of the patient's funding source and the specific health plan name, if applicable:
   a. Public insurance,
   b. Private insurance,
   c. Self-pay,
   d. Workplace monitoring program,
   e. Other, or
   f. Unknown;
6. The type of blood draw used (venous or capillary);
7. The date the blood was drawn;
8. The blood lead level;
9. The date the blood lead level was received by the physician or determined by the laboratory;
10. The name, address, and telephone number of the laboratory that tested the blood; and
11. The name, practice name, address, and telephone number of the physician who ordered the test.

Historical Note
New Section renumbered from R9-4-301 and amended by final rulemaking at 7 A.A.R. 55, effective December 12, 2000 (Supp. 00-4).

ARTICLE 4. CANCER REGISTRY

R9-4-401. Case Reporting

A. Case reports shall be submitted to the ACR by cancer clinics, doctors, and hospitals, except for behavioral and rehabilitation hospitals. Clinics seeing fewer than 100 cancer cases per year shall comply as per the requirements for doctors.

B. A case report shall be prepared on a form provided by the ACR and shall use standardized codes and coding format supplied by the ACR in the coding of the data items on the case report.
1. A full case report shall contain narrative and coded data that includes patient identification, demographic and diagnostic information, a chronological summary of the disease, stage, extent of disease, treatment, recurrence, vital status, names of doctors, reporting registrar and facility.
2. An abbreviated case report shall contain patient identification, demographic and diagnostic information, vital status and the names of the doctors.

C. Each year following the date of last contact, hospitals shall submit a follow-up report of each case to the ACR. Upon request of hospitals or the ACR, cancer clinics and doctors shall provide information available in office records for the follow-up report.

Historical Note
Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3).

R9-4-401.01. Pathology Laboratory Reporting

A. For the purposes of this Section, "pathology laboratory" means a location where human cells or tissue are examined for the purpose of diagnosing cancer.

B. A pathology laboratory shall permit the Department to review pathology reports once every 90 days to collect the information specified in R9-4-401(B) that is necessary for the Department to complete a case report.

Historical Note
New Section made by final rulemaking at 9 A.A.R. 1859, effective June 3, 2003 (Supp. 03-2).

R9-4-402. Filing Requirements

A. A hospital with 50 or more licensed beds shall appoint one or more cancer registrars who shall complete and submit a full case report for each case, whether inpatient or outpatient, diagnosed or admitted for the first time. The case report shall be submitted within 180 days from the date the case is discharged.

B. A hospital with less than 50 licensed beds shall either report as specified in subsection (A) or shall permit the staff of the ACR access to, and review of, the medical records of all patients with cancer for the purpose of completing a case report form. If the latter method of reporting is employed, the hospital shall provide the medical records for review every six months.

C. Cancer clinics shall submit an abbreviated case report to the ACR for each cancer case not immediately referred to a hospital. They shall designate a doctor or a registrar to submit the case report, if required, within 90 days of diagnosis or initiation of treatment at the facility.

D. Doctors shall utilize one of the following procedures to submit an abbreviated case report of any cancer case they diagnose but do not immediately refer for cancer treatment to a hospital or to a cancer clinic.

1. If a doctor receives a report form from the ACR, the doctor shall review the form, verify its accuracy, correct or complete any missing information, and resubmit it to the ACR within 30 days; or
2. If a doctor diagnoses cancer in an outpatient case without a record in a pathology laboratory licensed by the Department, the doctor shall initiate an abbreviated case report and submit it directly to the ACR within 30 days.

E. Within two years of the effective date of these rules, registrars at hospitals with 150 or more licensed beds, and cancer clinics submitting 100 or more case reports per year shall submit a paper copy of the case report and an IBM compatible 5 1/4 or 3 1/2 inch diskette that contains computer-readable data coded in accordance with R9-4-401. Diskettes from hospitals shall be submitted monthly. Diskettes from cancer clinics shall be submitted quarterly.

Historical Note
Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3).

R9-4-403. Data Quality Assurance

A. Upon notice of five business days in advance, records maintained by hospitals, cancer clinics and doctors shall be subject to review by the staff of the ACR to assure completeness and accuracy of the data reported.

B. Upon request by the ACR, hospital registrars shall abstract a standard medical record for the purpose of demonstrating the variability with which data is reported.

C. Reports not prepared in accordance with R9-4-401(B) shall be returned to the reporting entity for revision and resubmitted to the ACR within 15 days of date of receipt.

D. A hospital, cancer clinic or doctor shall satisfy the requirement for complete reporting of cases when 97% of the reportable cases in a calendar year are submitted to the ACR. The Department shall review the medical records to determine whether there has been compliance with this requirement.

E. Each hospital shall submit follow-up reports covering 90% of the total number of cases reported by that institution.

Historical Note
Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3).

R9-4-404. Repealed

Historical Note
Adopted effective January 1, 1992, filed September 25, 1991 (Supp. 91-3). Section repealed by final rulemaking at 9 A.A.R. 1859, effective June 3, 2003 (Supp. 03-2).

ARTICLE 5. BIRTH DEFECTS MONITORING PROGRAM

R9-4-501. Definitions

In this Article, unless otherwise specified:

1. "ABDMP" means the Arizona Birth Defects Monitoring Program within the Department.
2. "Birth defect" means an abnormality of structure, function, body chemistry, or gene present at or before birth, which may be diagnosed before or at birth, or later in life.
3. "CRS" means the Children's Rehabilitative Services program within the Department.
4. "Genetic testing facility" means an organization, institution, corporation, partnership, business, or entity that conducts tests to analyze and diagnose a genetic condition in a human being.
5. "Patient" means an individual admitted to or receiving care in a hospital, genetic testing facility, prenatal diagnostic facility, or the CRS.
6. "Personal identifiers" means confidential information that can be solely attributed to a specific individual.
7. "Prenatal diagnostic facility" means an organization, institution, corporation, partnership, business, or entity that conducts diagnostic ultrasound or other medical procedures that diagnose a birth defect in a human being.
8. "Reporting source" means a hospital, genetic testing facility, prenatal diagnostic facility, or the CRS.

Historical Note
Adopted effective September 25, 1991 (Supp. 91-3). Former Section R9-4-501 renumbered to R9-4-502; new Section R9-4-501 adopted by final rulemaking at 7 A.A.R. 712, effective January 17, 2001 (Supp. 01-1).

R9-4-502. Procedures; Permission to Review Patient Records

A. A reporting source providing care to an individual from fertilization to one year of age who has been diagnosed as having a birth defect shall permit the ABDMP to review and record personal identifiers, demographic, and diagnostic data from:

1. The following documents pertaining to the individual and the individual's mother:
   a. Disease indices,
   b. Intensive care unit logs,
   c. Pathology-autopsy logs for stillbirths,
   d. Patient medical records, and
   e. Laboratory reports pertaining to chromosomal analysis and tests for detection of hereditary biochemical disorders.
2. The labor and delivery logs and the ultrasound logs for the individual's mother.

B. A hospital shall prepare a disease index listing an ICD-9-CM diagnosis code for each patient identified in subsection (A) arranged in ascending order. Next to each ICD-9-CM diagnosis code listed in the index, the hospital shall provide the following information:

1. Whether the diagnosis code reflects a principal or secondary diagnosis,
2. The age of the patient,
3. The dates of admission and discharge, and
4. The patient's medical record number.

C. A reporting source shall permit ABDMP to review the documents listed in subsections (A) once every 30 days.

Historical Note

Adopted effective September 25, 1991 (Supp. 91-3). New Section R9-4-502 renumbered from R9-4-501 and amended by final rulemaking at 7 A.A.R. 712, effective January 17, 2001 (Supp. 01-1).